Designation Run Report

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357:10 - 359:01 **Walker, Donald 01-10-2019 (00:01:52)** V315A.1

357:10 Q. Good evening, Mr. Walker.
357:11 A. Good evening.
357:12 Q. Mr. Walker, you testified earlier
357:13 today that you joined McKesson in 1987; is that
357:14 correct?
357:15 A. That is correct.
357:16 Q. Before joining McKesson, where did
357:17 you work?
357:18 A. Prior to -- immediately prior to
357:19 working for McKesson, I worked for a grocery
357:20 wholesale distributor, a trucking company. And then
357:21 prior to that, I spent ten years in law enforcement.
357:22 Q. What roles did you play in law
357:23 enforcement?
357:24 A. I was a city police officer in a city
357:25 in the East Bay of San Francisco.
358:1 Q. Back to your time at McKesson. Could
358:2 you describe for the jury the various positions you
358:3 held at McKesson beginning in 1987.
358:4 A. 1987 I joined the company with a
358:5 subsidiary company in the transportation group,
358:6 transportation and warehousing. And that company
358:7 transitioned to the McKesson Drug Company in roughly
358:8 1991. Was in a staff role for a short period of
358:9 time, a staff role in transportation.
358:10 Then I became the Distribution Center
358:11 Manager in Sacramento, promoted to the Vice President
358:12 of Distribution Operations for the Western Region.
358:13 It was a newly-created position.
358:14 And subsequently, in roughly 1996, I was
358:15 promoted to the Senior Vice President of Distribution
358:16 for McKesson Pharmaceutical.
358:17 Q. And when did you become Senior Vice
358:18 President of Distribution for McKesson
358:19 Pharmaceutical?
358:20 A. It was 1996. I don't remember
358:21 exactly when in '96.
358:22 Q. And that was also the position you
358:23 held when you retired from McKesson; is that correct?

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	358:24 A. Yes, it was. 358:25 Q. When did you retire? 359:1 A. June of 2015.	
359:18 - 365:11	**Walker, Donald 01-10-2019 (00:09:07)** 359:18 Q. And briefly, what were your job 359:19 responsibilities as Senior Vice President of 359:20 distribution operations at McKesson? 359:21 A. I was the senior staff operations 359:22 person for McKesson. I had the overall 359:23 responsibility for the distribution network. 359:24 On my staff I had a support team made up of 359:25 a Transportation Group, an I.T. Support Group, our 360:1 Regulatory Affairs Group was in there, and I had a 360:2 group that was responsible for construction and 360:3 building of our distribution centers. 360:4 Q. You mentioned Regulatory Affairs. 360:5 What kind of regulatory affairs matters were you 360:6 responsible for as Senior Vice President of 360:7 operations -- distribution operations, I should say? 360:8 A. McKesson, and the wholesalers as an 360:9 industry, are highly regulated. We have 360:10 responsibilities for a number of regulatory 360:11 requirements. The FAA, the Department of 360:12 Transportation, DOT, OSHA. We had hazardous material 360:13 requirements. Certainly we had responsibility for 360:14 compliance with DEA regulations. And various state 360:15 and local regulations as well. 360:16 Q. What was involved in the handling of 360:17 controlled substances in particular? 360:18 A. Our -- our distribution network in 360:19 handling controlled substances was complex. The 360:20 requirements under the federal code ensure -- wanted 360:21 to ensure that we had systems in place to prevent 360:22 diversion, primarily around security, as the code 360:23 spelled out. 360:24 And so the inside of our buildings, the 360:25 controlled substances divided into two major areas. 361:1 One, in what we called the narcotics Class 2 361:2 controlled substances were stored in a vault, much 361:3 like a bank vault, and the balance of the controlled	V315A.2

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361:4 substances were stored in a locked and secured cage.
361:5 There was requirements for alarm. The physical --
361:6 the physical construction of both the vault and the
361:7 cage were specified under regulation.
361:8 And, in addition, we had reporting
361:9 requirements to the DEA, the ARCOS reporting, which
361:10 was the month-end reporting of all of our sales. We
361:11 needed to reconcile all of our receipts and all of
361:12 our sales and our inventory, along with the physical
361:13 inventory, to ensure that we could account for each
361:14 and every one of the controlled substances that was
361:15 in our possession that was reportable.
361:16 We had reporting requirements on suspicious
361:17 orders. Our suspicious order reporting we called at
361:18 the time -- prior to 2008 we gave it a moniker that
361:19 said -- basically a report number called DU45, and we
361:20 provided that suspicious order reporting to the local
361:21 DEA field offices, as required.
361:22 Q. And you described the DU45 report.
361:23 What was the DU45 report exactly?
361:24 A. The DU45 was a report that reviewed
361:25 sales of customers' purchases of controlled
362:1 substances. And based on an algorithm that had been
362:2 developed many years ago, I'm not sure when,
362:3 identified any sales that might have been of unusual
362:4 size, frequency, or a pattern, to ensure that we were
362:5 complying with that portion of the Federal
362:6 Regulation.
362:7 Q. And over what period did McKesson
362:8 generate the DU45 report for the purpose of reporting
362:9 to DEA?
362:10 A. I'm not certain when we started to
362:11 provide that report. But during my tenure there,
362:12 we -- at McKesson we provided that report up until
362:13 the 2008 time frame, at which time, as a result of
362:14 our Settlement Agreement with DEA, we ceased
362:15 providing that report to the DEA.
362:16 Q. When you first became Senior Vice
362:17 President of Distribution Operations back in 1996,
362:18 what was McKesson's relationship with the DEA like?

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362:19 A. I think I would best describe that
362:20 relationship as collaborative. On a regular basis
362:21 our distribution centers could engage local field
362:22 offices on inquiries and questions.
362:23 Conversely, DEA would contact us at a
362:24 headquarters level, our senior management, my
362:25 predecessor. And my regulatory team could pick up
363:1 the phone and have conversations back and forth with
363:2 the DEA regarding various matters.
363:3 Q. And how, if at all, did McKesson's
363:4 relationship with the DEA change over time?
363:5 A. Well, in the -- it clearly in the
363:6 2005 -- late 2005/2006 time frame, after the new
363:7 administrator was in place, I would say McKesson's
363:8 relationship with DEA became more confrontational.
363:9 Q. And you described earlier to
363:10 Mr. Kennedy that you had a five-year period, I think
363:11 it was, when you ran McKesson's Six Sigma program; is
363:12 that correct?
363:13 A. That's correct. Roughly, in 2000 to
363:14 2005 I was not the Senior Vice President of
363:15 Operations, Distribution Operations, and did not have
363:16 responsibility for Regulatory during that time frame,
363:17 but was responsible for our Six Sigma process
363:18 improvement.
363:19 Q. So starting with your return to the
363:20 Senior Vice President of Distribution Operations'
363:21 position in 2005, what interactions did you
363:22 personally have with DEA?
363:23 A. The first personal interaction I had
363:24 with DEA was the -- was the January 6, 2000 -- or
363:25 excuse me, January 2006 meeting that we had in
364:1 Washington, D.C., in which we reviewed the Florida
364:2 and the Internet pharmacies and -- with
364:3 Mr. Rannazzisi and other members of his staff.
364:4 Q. Who -- other than the people you just
364:5 mentioned, who attended that January 2006 meeting?
364:6 Maybe starting from McKesson.
364:7 A. My recollection is I attended; Bill
364:8 Mahoney, who was our Distribution Center Manager in

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364:9 Florida; John Gilbert, who is our outside counsel;
364:10 and I believe that Gary Hilliard, who was on our
364:11 Regulatory team, also participated in that meeting
364:12 from McKesson.
364:13 From DEA, Mr. Rannazzisi, their outside
364:14 counsel, and one or two other members of his
364:15 Diversion Control staff.
364:16 Q. What message did you take out of the
364:17 January 2006 meeting at DEA headquarters?
364:18 A. I -- the messages that I took out
364:19 were several. First and foremost, was DEA's concern,
364:20 it was very clear to us, over the Internet pharmacies
364:21 that they identified in Florida. You know,
364:22 Mr. Rannazzisi unexpectedly asked to have us
364:23 surrender our DEA registration for our Florida
364:24 Distribution Center.
364:25 And in the course of discussions, there were
365:1 a couple of key themes that came out. One is that we
365:2 had a responsibility to -- which it, quite frankly,
365:3 was the first that we had ever heard from DEA that
365:4 we -- you know, his statement was, why would you ever
365:5 ship an order that you identified as suspicious? And
365:6 he viewed our DU45 report as inadequate and not
365:7 meeting the -- their needs.
365:8 He -- and, again, this is the first that we
365:9 had had any indication, after many, many years of
365:10 providing it, that there was any concern over our
365:11 DU45, our suspicious order reporting.

365:23 - 366:10 **Walker, Donald 01-10-2019 (00:00:53)** V315A.3

365:23 Q. And so in the area of suspicious
365:24 order reporting, what was the message you received
365:25 from DEA at the January 2006 meeting?
366:1 A. I came away from there that -- with a
366:2 very clear view that report only orders that are
366:3 truly suspicious. That the requirement for -- the
366:4 bar for reporting suspicious orders, because of his
366:5 statement that, you know, we -- a suspicious order, a
366:6 suspicious customer should not receive any controlled
366:7 substances, we went away from there with a very
366:8 serious view around correlating the suspicious orders

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	366:9 with ceasing selling controlled substances to a 366:10 customer.	
366:22 - 368:12	**Walker, Donald 01-10-2019 (00:02:40)** 366:22 Q. And you mentioned that some of these 366:23 messages, it was the first time you had heard these 366:24 things. And could you describe your reaction to 366:25 these messages that you've explained today. 367:1 A. Well, the first reaction I had was it 367:2 was significantly different than the interaction that 367:3 we had had with DEA in the past. It was clear that 367:4 there was a different view of the distributors. And 367:5 from that we really made the determination that we 367:6 needed to go back and follow up and review our 367:7 processes and our -- in order to try to, you know -- 367:8 the message was, from the DEA, is that there's an 367:9 issue. We're trying to solve it. 367:10 Our view was, is we've always collaborated 367:11 with DEA. So I took what was being said and tried 367:12 to, without specific guidance from them, to establish 367:13 a go-forward modification to our overall monitoring 367:14 program. 367:15 Q. So did you take -- why don't you 367:16 describe any actions that you took following up on 367:17 that January 2006 meeting and the messages that you 367:18 received. 367:19 A. Specifically after the meeting in 367:20 2007, we went back, and we immediately conducted 367:21 additional review and site visits to the pharmacies 367:22 that they had identified to us during the meeting. 367:23 We subsequently ceased selling controlled 367:24 substances to those pharmacies and reported such to 367:25 the DEA. Even though the -- you know, we learned 368:1 that the DEA didn't make any changes in their DEA 368:2 registration, but we made the choice to cease selling 368:3 controlled substances to them. 368:4 We initiated -- we went back and initiated 368:5 the development of a new program, which evolved into 368:6 what we called the LDMP, which was the Lifestyle Drug 368:7 Monitoring Program. And primarily named because 368:8 during the meeting the DEA had used the term	**V315A.4**

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	368:9 "lifestyle drugs" to identify four drugs of concern 368:10 that they identified as part of the Internet 368:11 pharmacy, being the oxycodone, the hydrocodone, 368:12 pyrazoline and Phentermine.	
368:13 - 368:21	**Walker, Donald 01-10-2019 (00:00:40)** 368:13 MS. HENN: I'd like to show you an exhibit. 368:14 Let's get this marked as 84. 368:15 THE REPORTER: 804. 368:16 MS. HENN: 804. Thank you. 368:17 (Exhibit No. 804 was marked.) 368:18 BY MS. HENN: 368:19 Q. Mr. Walker, the court reporter handed 368:20 you an Exhibit No. -- that's been marked 804. The 368:21 Bates number is -571361 through -65.	**V315A.5**
369:08 - 371:07	**Walker, Donald 01-10-2019 (00:02:18)** 369:8 Q. What is Exhibit 804? 369:9 A. This is a letter from Paul Julian, 369:10 our President, one of the senior members of McKesson, 369:11 to Mr. Rannazzisi in response to the meeting that we 369:12 had with DEA, in which he -- at a high level what he 369:13 has done is summarize the actions that we have taken, 369:14 how seriously we viewed the meeting, and how 369:15 seriously we reviewed -- or viewed our regulatory 369:16 obligations, and provided him examples of actions 369:17 that we had taken subsequent to the meeting. 369:18 Q. And at the time this letter was sent 369:19 to Mr. Rannazzisi, did you receive a copy of this 369:20 letter? 369:21 A. Yes, I did. I was -- I believe I was 369:22 copied on the letter. 369:23 Q. On the -- 369:24 A. Yes. Yes, I was. 369:25 Q. Okay. Turning to the second page of 370:1 the letter, page 2. Could you read what McKesson's 370:2 Mr. Julian writes to Mr. Rannazzisi in the first 370:3 paragraph. 370:4 MR. KENNEDY: Objection. 370:5 THE WITNESS: (Reading) In this regard I 370:6 must rebut any impression that 370:7 McKesson has not seriously considered	**V315A.6**

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	370:8 and responded to the information 370:9 provided by DEA about the 370:10 management -- about the problem of 370:11 "Internet pharmacies." After the 370:12 September meeting with DEA, senior 370:13 management responsible for all 370:14 McKesson distribution centers were 370:15 provided with the -- with a summary of 370:16 the issues raised by the DEA about 370:17 Internet pharmacies and DEA's view of 370:18 what constitutes an illegal Internet 370:19 pharmacy. Additionally, discussions 370:20 on the appropriate next steps were 370:21 reviewed and included running regional 370:22 sales reports based on the criteria 370:23 provided by DEA. At the September 370:24 meeting, DEA identified Colorado 370:25 pharmacies by name. Upon notification 371:1 that DEA had suspended the 371:2 registration of these pharmacies, 371:3 McKesson immediately terminated the 371:4 authority for these Colorado 371:5 pharmacies to order controlled 371:6 substances from McKesson (end of 371:7 reading).	
371:21 - 371:24	**Walker, Donald 01-10-2019 (00:00:15)** 371:21 Q. Moving down to the paragraph -- the 371:22 third paragraph on this page, starting with, "On 371:23 November 21st, 2005." Could you read that paragraph 371:24 that Mr. Julian wrote to Mr. Rannazzisi at the DEA.	**V315A.7**
372:01 - 373:24	**Walker, Donald 01-10-2019 (00:02:13)** 372:1 THE WITNESS: (Reading) On November 21st, 372:2 2005, DEA notified McKesson through 372:3 outside counsel that DEA was extremely 372:4 concerned about excessive distribution 372:5 of hydrocodone products to six 372:6 specific pharmacies in the Tampa, 372:7 Florida area. There's a footnote. 372:8 McKesson immediately imposed a 372:9 limitation on all of these pharmacies	**V315A.8**

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372:10 and cut the sales of hydrocodone to
372:11 these pharmacies to only 10 percent of
372:12 their prior orders. McKesson also
372:13 began an investigation of all these
372:14 pharmacies which included requesting
372:15 additional information from the
372:16 pharmacies about their customers and
372:17 steps taken to verify that their --
372:18 that the prescriptions filled are
372:19 legitimate. McKesson sales managers
372:20 have been visiting the accounts
372:21 inquiring into the nature of their
372:22 business activity (end of reading).
372:23 BY MS. HENN:
372:24 Q. And you mentioned there's a footnote
372:25 in that paragraph. If you could read that footnote
373:1 to yourself. My question for you is whether you're
373:2 familiar with what's described in Footnote 1?
373:3 A. Yes. During -- during this same time
373:4 frame, there was a number of different events that
373:5 were affecting the country. Hurricane Katrina had
373:6 just gone through, and specifically in Tampa, Florida
373:7 and Northern Florida was -- hurricane Wilma was
373:8 coming through. It was our normal practice with
373:9 customers where we anticipate, particularly with
373:10 hurricanes, where we anticipate that there was going
373:11 to be a business interruption due to the storm, for
373:12 them to ensure that they ordered in advance and
373:13 stocked their pharmacies so that after the hurricane
373:14 passed, that they could come up back into business as
373:15 quickly as possible, particularly because their --
373:16 the need becomes very great post hurricanes for
373:17 certain medications.
373:18 And there was a concern expressed around the
373:19 quantities to one of the pharmacies, United
373:20 Prescription, where we sold a significant quantity in
373:21 a short amount of time. But at the same time, right
373:22 after the hurricane passed, and subsequent to that,
373:23 the volume that the pharmacy purchased dropped
373:24 dramatically.

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374:02 - 375:19	**Walker, Donald 01-10-2019 (00:02:54)**	V315A.9

374:2 Q. Mr. Walker, setting aside this
374:3 letter. In your testimony a few minutes ago, you
374:4 referred to the Lifestyle Drug Monitoring Program.
374:5 Could you describe the general contours of the
374:6 Lifestyle Drug Monitoring Program.
374:7 A. We -- this was really the beginning
374:8 of our overall control of the monitoring program. We
374:9 focused on the four lifestyle drugs that had been
374:10 identified in the January meeting. We established a
374:11 mechanism of thresholds DEA had shared with us in
374:12 the -- in the meetings that we had had, that they
374:13 viewed that the average pharmacy purchases per month
374:14 for a given -- for across the nation for these
374:15 certain drugs is about 5,000 dose units.
374:16 Our own internal data we reviewed, it was --
374:17 the average was closer to 8,000 dose units for our
374:18 customer base. And we then used the information, the
374:19 data, to establish these thresholds.
374:20 We then ran -- we monitored the sales in
374:21 terms of dose units purchased, which required a
374:22 significant change in -- from a systems standpoint
374:23 because we had to combine all of the individual
374:24 items, unique items, that constitute a given base
374:25 code. So basically all the brand, generic, all the
375:1 items that were, for example, hydrocodone, had to be
375:2 collated together and multiplied out in terms of the
375:3 base -- the dose units. A complex process.
375:4 But we -- we then ran reports on a monthly
375:5 basis to ensure that it identified any customers that
375:6 exceeded their threshold. From that we conducted
375:7 additional follow-up, and to review. And we also
375:8 instituted our -- the beginning of our questionnaire
375:9 process for new customers and the regulatory review
375:10 process that evolved into CSMP.
375:11 Q. Why did you take these actions
375:12 following the January 2006 meeting with DEA?
375:13 A. It was our -- our intent to be very
375:14 responsive to -- we had long taken guidance from DEA
375:15 and taken it seriously. So from that meeting, we

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	375:16 determined that we needed to take actions that would 375:17 address the issues that were raised by DEA during 375:18 that meeting. And that was, you know, a very focused 375:19 part of our effort.	
381:02 - 382:08	**Walker, Donald 01-10-2019 (00:02:10)** 381:2 You have described the Lifestyle Drug 381:3 Monitoring Program. Earlier today Mr. Kennedy asked 381:4 you a lot of questions about the next program that 381:5 McKesson developed. That was called what? 381:6 A. The Controlled Substance Monitoring 381:7 Program, or CSMP. 381:8 Q. What was the difference between the 381:9 new CSMP program that was put into place and the 381:10 LDMP, or Lifestyle Drug Monitoring Program? 381:11 A. There were a number of things that -- 381:12 that were done at that time. First, the difference 381:13 specifically in the programs is we continued to use 381:14 the concept of thresholds to monitor specific orders. 381:15 The significant difference was that we created a 381:16 systemic solution to total the dose units purchased 381:17 by a given pharmacy on a given controlled 381:18 substances -- substance. And if the order that was 381:19 generated at any given time caused the pharmacy to go 381:20 above the threshold, that entire order was blocked. 381:21 The blocking of orders was a piece. 381:22 We had -- we continued to have the 381:23 three-part review. The difference being is that the 381:24 blocked order triggered a review process, but we 381:25 still maintained a three-tiered escalation process 382:1 and how we would report to the DEA. 382:2 We enhanced the questionnaire and document. 382:3 And it -- outside of specifically the CSMP, but our 382:4 overall regulatory effort, we invested, well, 382:5 significantly in the I.T. effort to solve the CSMP 382:6 I.T. side, but we also expanded our regulatory force, 382:7 adding the four new directors of Regulatory Affairs, 382:8 one assigned to each region.	**V315A.10**
383:03 - 384:02	**Walker, Donald 01-10-2019 (00:01:29)** 383:3 Q. As this development effort was 383:4 underway to develop a new system of suspicious order	**V315A.11**

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383:5 reporting between McKesson's I.T. and the DEA's I.T.
383:6 people, how did McKesson report suspicious orders in
383:7 that interim period?
383:8 A. We -- we continued to submit the DU45
383:9 to local field offices. And, in addition, as we
383:10 identified customers that we had done the due
383:11 diligence, who had gone through our three-tiered
383:12 review, and we had made a determination that we were
383:13 no longer going to sell controlled substances to
383:14 these customers, we reported those to DEA.
383:15 And the way -- in fact, I did that work. I
383:16 would contact DEA directly to ensure that they were
383:17 aware of the actions we were taking and ensure that
383:18 they knew that we were reporting those suspicious --
383:19 those orders and customers to them.
383:20 Q. And you mentioned that the DU45s were
383:21 continued -- McKesson continued to send those while
383:22 the new system was in development. When did McKesson
383:23 cease providing DU45 reports to the DEA?
383:24 A. I think in January of '09, we finally
383:25 reached mutual agreement that we had a system that
384:1 could talk back and forth. And I think in January of
384:2 2009 is when we ceased providing DU45.

384:07 - 384:22 **Walker, Donald 01-10-2019 (00:00:55)** V315A.12

384:7 Q. Mr. Walker, you've been handed
384:8 Defense Exhibit 806, which is Bates
384:9 No. McKesson-WVA-167.
384:10 Do you recognize this document?
384:11 A. Yes, I do.
384:12 Q. What is this?
384:13 A. This is a memo from -- or an email
384:14 memo from me to our field distribution teams and
384:15 distribution centers advising them that -- this is
384:16 dated January 22nd of '09 -- that we would no longer
384:17 be providing the DEA with the end-of-month DU45 or
384:18 the Suspicious Order Report, and that our new
384:19 reporting mechanism was in place and established as
384:20 part of our agreement with DEA, and directed the DCs
384:21 not to submit those reports to the local field
384:22 offices.

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385:01 - 385:02	**Walker, Donald 01-10-2019 (00:00:04)**	V315A.13
	385:1 A. It was part of our settlement 385:2 agreement that we agreed to.	
387:07 - 387:23	**Walker, Donald 01-10-2019 (00:00:55)**	V315A.14
	387:7 Q. Mr. Walker, who at McKesson was 387:8 responsible for setting up the electronic reporting 387:9 system that was put into place after the 2008 387:10 Settlement Agreement with DEA? 387:11 A. Working on my -- on my team, on my 387:12 I.T. group, was a lady named Jenny Melton. She was 387:13 the project lead and coordinator, and she was the 387:14 direct contact with the DEA contact from the I.T. 387:15 side. 387:16 Q. And at the time Ms. Melton was 387:17 working on this project, were you from time to time 387:18 aware of communications back and forth between 387:19 Ms. Melton and her counterpart at DEA? 387:20 A. At a high level, yes, I was aware. I 387:21 was aware that there was actually fairly frequent 387:22 conversations back and forth between Jenny and the 387:23 I.T. team at DEA.	
388:04 - 392:05	**Walker, Donald 01-10-2019 (00:06:48)**	V315A.15
	388:4 Q. So, Mr. Walker, you've been handed a 388:5 document marked Defense Exhibit 808. The Bates 388:6 number is MCK-WVA-139. And this is a somewhat 388:7 lengthy chain of emails, but I'll ask you if you 388:8 recognize it? 388:9 A. Yes, I've seen this document before. 388:10 Q. What is the date on which you 388:11 received this email chain? 388:12 A. I received the email chain on 388:13 November 4th of 2008. 388:14 Q. And what is it exactly? 388:15 A. This is a document, and attached is 388:16 an email from DEA to Jenny, some of which was 388:17 specific in terms of the data details of the I.T. 388:18 systems that they were -- really in direct response 388:19 to some questions that Jenny had, I think, to the 388:20 individual was Noel Goretsas, who, if I recall, was 388:21 the I.T. lead for DEA.	

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388:22 Q. So you're looking at page 2 of the
388:23 email, from Noel Goretsas, at the DEA, to Jenny
388:24 Melton, at McKesson, your I.T. lead?
388:25 A. Yes.
389:1 Q. What information did DEA, through
389:2 Noel Goretsas, communicate to Jenny Melton in the
389:3 course of this work to set up the electronic system
389:4 about suspicious order reporting?
389:5 A. There were -- there were a couple of
389:6 questions that were answered. In looking at the page
389:7 -142, it provided the technical view on the
389:8 characters or basically the I.T. format, but also
389:9 stated that a suspicious order should be reported to
389:10 DEA only after your company has completed its due
389:11 diligence and determine that you will not complete
389:12 the sale because it is suspicious. Stating that
389:13 suspicious orders are not sales or potential sales.
389:14 And there was some other discussion around
389:15 suspicious orders. And then he noted that, report a
389:16 suspicious order as soon as your company had decided
389:17 that they will not make the sale because it is
389:18 suspicious.
389:19 Q. So was this -- were these -- was this
389:20 guidance that Mr. Goretsas was providing to McKesson
389:21 consistent with what you had heard, even dating back
389:22 to the January 2006 meeting you described with
389:23 Mr. Rannazzisi and the others from the DEA?
389:24 A. Yes, it was -- it was consistent with
389:25 the messaging that I heard in the 2006 meeting.
390:1 Q. And what did this guidance from DEA
390:2 mean, in terms of the suspicious order reporting that
390:3 McKesson would be making to the DEA, if you compare
390:4 the old DU45 system and this new system put in place
390:5 pursuant to this guidance?
390:6 A. First, is that the numbers of
390:7 suspicious orders that we would report would be
390:8 significantly less because the methodology in which
390:9 we were determining whether something was suspicious
390:10 was far more involved.
390:11 We would also, in the course of this, be

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390:12 answering their question around ensuring that we were
390:13 providing them with usable information.
390:14 And those were our primary intents, was to
390:15 ensure that our suspicious order reporting was
390:16 complying with what -- what limited information they
390:17 provided us in that January 6 meeting.
390:18 Q. And under the new system McKesson put
390:19 in place pursuant to this guidance from DEA, what was
390:20 the frequency of the reports of suspicious orders?
390:21 A. I don't know that I can answer it in
390:22 terms of a specific frequency, other than there were
390:23 a lot fewer Suspicious Order Reports going -- going
390:24 to DEA.
390:25 Q. Did this make sense to you?
391:1 A. Yes, it did.
391:2 Q. Why?
391:3 A. My view was that we were -- in our
391:4 suspicious order and our Controlled Substance
391:5 Monitoring Program, we were really focused on
391:6 identifying pharmacies that after the due diligence
391:7 we had a high degree of confidence were not
391:8 necessarily complying with their regulatory
391:9 obligations and potentially diverting controlled
391:10 substances. And we created as a -- as a very high
391:11 standard to report the term suspicious order. And
391:12 suspicious -- and with that, it just reduced the
391:13 number of customers or pharmacies that we were
391:14 reporting to the DEA. And very specifically trying
391:15 to provide them with as much information and expedite
391:16 the process in their respective enforcement
391:17 activities.
391:18 Q. And you've described that under the
391:19 new system put in place pursuant to the DEA guidance,
391:20 there would be -- the frequency of suspicious order
391:21 reporting and the number of Suspicious Order Reports
391:22 would be fewer or less.
391:23 Was there any change to the other types of
391:24 reporting that you, McKesson, provided to DEA, that
391:25 you've described today?
392:1 A. No. I mean, the ARCOS reporting

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	392:2 requirement remained the same. We continued to 392:3 report and supply DEA with all of the ARCOS data 392:4 throughout this process. The ARCOS reporting was 392:5 uninterrupted and not changed.	
395:08 - 395:15	**Walker, Donald 01-10-2019 (00:00:33)** 395:8 After McKesson's Controlled Substance 395:9 Monitoring Program was in place, did you have further 395:10 interaction with the DEA about the program? 395:11 A. Yes, I did. In July of 2008, shortly 395:12 after the settlement, we requested a meeting with DEA 395:13 at DEA headquarters so that we could review our 395:14 Controlled Substance Monitoring Program with them in 395:15 some -- in some detail.	**V315A.16**
396:07 - 400:04	**Walker, Donald 01-10-2019 (00:05:52)** 396:7 Q. What is Exhibit 812, if you recognize 396:8 it? 396:9 A. I recognize this. This is a 396:10 PowerPoint presentation that I created for the 396:11 meeting that we had with DEA in July of 2008. 396:12 Q. Did -- who created this document? 396:13 A. I created the document. 396:14 Q. And what did you use this document 396:15 for? 396:16 A. We made -- and I say "we." There 396:17 were people from McKesson that met with members of 396:18 the DEA Diversion Team in Washington, D.C. at their 396:19 headquarters, and the intent of this document was to 396:20 review with them in some level of specifics the way 396:21 that we had designed the program, how it was being 396:22 executed, and what we were -- we were going to do 396:23 with our Controlled Substance Monitoring Program. 396:24 Q. Who was present at the July 31st, 396:25 2008, meeting, starting from the DEA this time, if 397:1 you remember? 397:2 A. My recollection was -- well, Kyle 397:3 Wright was there from DEA. And I believe Maureen 397:4 O'Keefe. And if I'm not mistaken, I believe I recall 397:5 that Barbara Boockholdt, all of which were members of 397:6 the diversion team. And there were some other 397:7 members that may have been present, one or two other	**V315A.17**

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397:8 people.
397:9 Q. And from McKesson?
397:10 A. It was myself and counsel. I don't
397:11 remember if there were any other McKesson members
397:12 there.
397:13 Q. Could you turn to page 4 of the slide
397:14 presentation. What were the components of the CSMP
397:15 that you discussed with DEA at the meeting?
397:16 A. Components at a high level was --
397:17 really, the meat of the program was knowing your
397:18 customer, which would include the questionnaire and
397:19 the information that we would gather about the
397:20 customer and their business.
397:21 Establishing thresholds, you know, how we
397:22 would establish thresholds based on customers.
397:23 Again, knowing the customer, the size of the
397:24 pharmacy, the business that they -- they had, whether
397:25 they were supporting an orthopedic clinic or had a
398:1 nursing home oncology, all of the things that can
398:2 drive a variation in prescriptions.
398:3 We were going to monitor our orders against
398:4 the thresholds that we established, you know, for the
398:5 customers, and that we would block any orders that
398:6 exceeded the threshold. So, again, if the order came
398:7 through, and that quantity ordered exceeded the
398:8 threshold, the order was blocked.
398:9 A. review and escalation process. Once the
398:10 blocked order was in place, how we would report
398:11 suspicious orders and any other reports, and offered
398:12 up any other analysis or reports the DEA could
398:13 identify that could help them in their enforcement
398:14 activities.
398:15 Q. And turning to page 6, slide 6 of
398:16 your presentation to the DEA.
398:17 What did you tell the DEA about steps that
398:18 McKesson was going to take with respect to existing
398:19 customers?
398:20 A. We -- there were -- there were
398:21 several points that we covered with DEA, that from an
398:22 existing customer standpoint, we would establish the

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	398:23 thresholds. We would review their 12-month purchase 398:24 history. We would establish default volumes or 398:25 quantities in each one of the controlled substances. 399:1 We emphasized that unlike the LDMP, that the CSMP 399:2 covered all of the controlled substances that we 399:3 distributed. 399:4 There's a lot of focus around the controls 399:5 that have been abused, but there is a total of -- if 399:6 I recall, somewhere in the area of the mid 80s, 399:7 different control base-codes that we also managed 399:8 under this program. 399:9 So we had to establish, and we explained to 399:10 them we had to establish thresholds for every base 399:11 code for every customer that we had. 399:12 We indicated that we were going to conduct 399:13 site visits to customers, and based on priority. 399:14 They had in the meetings communicated to us that 399:15 their primary concern in pharmacies that had to 399:16 date -- to that date, had displayed the greater 399:17 propensity for illegal -- what they called illegal 399:18 activity, were independent pharmacies. So we viewed 399:19 that we needed to prioritize the independents first, 399:20 focusing on the lifestyle drugs, and ensuring that we 399:21 understood, you know, where pharmacies had dose 399:22 quantities that were greater than 25,000. 399:23 We were also clear with them at the time 399:24 that we -- how we were going to interact with our 399:25 retail national accounts. That we would utilize the 400:1 retail national accounts' internal regulatory and 400:2 loss prevention security organizations to assist us 400:3 as a insight into their pharmacy practices and their 400:4 overall control.	
400:23 - 406:20	**Walker, Donald 01-10-2019 (00:08:51)** 400:23 Q. And turning to page -- slide 9. What 400:24 did you communicate with DEA during the July 2008 400:25 meeting about the blocking of orders under the CSMP 401:1 program at McKesson? 401:2 A. In the meeting and in discussions 401:3 with them, that we explained very clearly that we 401:4 would block the orders that exceeded threshold. That	**V315A.18**

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401:5 it was specific to the base code and specific to the
401:6 registrant.
401:7 And that was a critical piece because many
401:8 customers have in our system multiple customer
401:9 numbers. And the DEA's -- in prior meetings it had
401:10 expressed some concern of making sure that we
401:11 understood all the sales that went to a customer.
401:12 So we made sure that they understood it was
401:13 specific to their registrant, which is a unique
401:14 number for the DEA, even though there might be
401:15 multiple McKesson customer numbers.
401:16 There was no override. There was not going
401:17 to be any override capability. Any changes in the
401:18 threshold would be -- would be required. And then a
401:19 threshold change process was going to be implemented
401:20 to adjust any thresholds with the documentation.
401:21 And the customer notification, we were very
401:22 clear that we would notify -- that DEA -- the DEA
401:23 that we would alert the customer if they were
401:24 approaching their threshold along with the -- an
401:25 invoice notification so that the customers were aware
402:1 and -- and, again, explained to them the issues that
402:2 we had with ensuring the customers had the ability to
402:3 fulfill their orders for their patients when the
402:4 orders were absolutely critical and necessary for
402:5 fulfilling scripts.
402:6 Q. Turn to slide 13. What information
402:7 did you provide to DEA during this July 2008 meeting
402:8 about the suspicious order reporting component of the
402:9 CSMP?
402:10 A. We communicated that -- we understood
402:11 that there was still the ongoing work that we were
402:12 prepared to stop, the DU45 reporting to DEA Field
402:13 Offices at the time that they agreed and we agreed --
402:14 and primarily they agreed that the format was
402:15 acceptable to them in terms of the reporting.
402:16 There was -- there certainly was a lot of
402:17 contact with DEA around the format and the -- and the
402:18 process that we were going to go through. And,
402:19 again, what we were trying to be is -- in this

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402:20 meeting, was clear with them that if there was a
402:21 concern or there's other information that we needed
402:22 to have, that they could provide it.
402:23 And, quite frankly, one of the other things
402:24 we asked is to get feedback and create a feedback
402:25 process on orders that were reported. We -- we
403:1 wanted to understand the effectiveness of our
403:2 reporting and our CSMP to understand whether we were
403:3 providing them the information that they needed to
403:4 manage their enforcement responsibilities for
403:5 pharmacies.
403:6 Q. Did DEA provide that feedback that
403:7 McKesson requested?
403:8 A. No, they did not.
403:9 Q. What was the DEA's reaction to all of
403:10 this information that you provided during the July
403:11 2008 meeting about the new CSMP program you put into
403:12 place?
403:13 A. My -- my recollection of the meeting
403:14 was that the DEA was -- well, first, they -- it is
403:15 not their habit nor did I expect them to provide a
403:16 stamp of approval on it. But their -- overall the
403:17 types of discussion and the questions were positive.
403:18 There was, you know, a fair amount of body language.
403:19 So my takeaway was, is that they were
403:20 satisfied with the -- with what we had presented to
403:21 them. And additionally, there wasn't any "you missed
403:22 it." There was no direction from them that we had
403:23 failed in meeting any of the components of the
403:24 Memorandum of Agreement, nor did they provide any
403:25 specific guidance at all on the -- on the program or
404:1 what we could do differently, better, et cetera.
404:2 Q. Did you have any follow-up meetings
404:3 about the CSMP with the DEA after this July 2008
404:4 meeting, that you recall?
404:5 A. Well, during -- during the meeting
404:6 that we had with DEA, we -- we asked -- and, again,
404:7 the reason we asked is that they were clear around
404:8 wanting to have more centralized control over
404:9 suspicious order reporting.

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404:10 But what we wanted to do was we wanted to go
404:11 to local field offices and share with the local field
404:12 offices what we were doing with our Controlled
404:13 Substances Monitoring Program. We did that. We took
404:14 an offshoot of this document and provided that to the
404:15 DRAs so that they could, in fact, have meetings with
404:16 the local field offices if the field office wanted to
404:17 do that. We reached out to them.
404:18 We made a number of presentations to local
404:19 field offices by way of the DRAs. I'm not sure
404:20 exactly how many. But we did do that. And,
404:21 actually, the document that I reviewed with
404:22 Mr. Kennedy earlier, I think is actually a copy of
404:23 the document we shared with the local field offices.
404:24 Q. And did you get any feedback from
404:25 those local field offices that reached you about the
405:1 2008 -- or about the CSMP that McKesson put in place
405:2 in 2008?
405:3 A. I didn't get any specific feedback
405:4 from the field office personally. The DRAs reported
405:5 a generally positive response, again, not unlike like
405:6 what we experienced in Washington, D.C.
405:7 Q. You've described your meeting at the
405:8 headquarters and then the DRAs' meetings that
405:9 occurred at local field offices. What, if any, other
405:10 interactions did McKesson have on an ongoing basis
405:11 with DEA and its distribution centers?
405:12 A. Well, throughout this process, there
405:13 is what I would call a lot of business as usual
405:14 interactions that McKesson distribution centers had
405:15 with the local field offices. Inquires around DEA
405:16 registrations of pharmacies, you know, around
405:17 expiration dates. Those are always a problem with
405:18 the DEA.
405:19 If there was a report -- there needed to be
405:20 a report of a theft or a loss, you know, questions
405:21 around -- and procedural things, in particular around
405:22 the paperwork, the ARCOS reporting. And the
405:23 paperwork required with that sometimes can be
405:24 confusing. So there's an ongoing relationship, just

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	405:25 an interactive relationship. 406:1 Additionally, the DEA continued to conduct 406:2 their cyclical audit. A cyclical audit is where the 406:3 DEA comes in unannounced and inspects the 406:4 distribution center in a number of different areas, 406:5 primarily around the recordkeeping, the security of 406:6 the controlled substances, the handling, reviewing 406:7 the associates that are authorized to handle 406:8 controlled substances. All of that is part of the 406:9 normal cyclical audit. 406:10 Q. And what would happen if DEA found an 406:11 issue during one of those cyclical audits? 406:12 A. Excuse me. There was an Audit Report 406:13 that was generated out of each one of the audits. If 406:14 there were actions that needed to be taken by 406:15 McKesson to correct anything that they identified in 406:16 the audit, virtually all the time that I can recall, 406:17 those were fairly minor issues. They were more what 406:18 I would call procedural. 406:19 We made the procedural adjustments and 406:20 reported back to DEA the changes that we made.	
408:24 - 410:13	**Walker, Donald 01-10-2019 (00:02:41)** 408:24 Q. Mr. Walker, you were asked by 408:25 Mr. Kennedy about -- I think you referred to them as 409:1 RNA chains, retail national accounts, like Rite Aid 409:2 and CVS. Could you describe how McKesson performed 409:3 due diligence on orders by chain pharmacies. 409:4 A. McKesson, as we had clearly indicated 409:5 in our program, was going to utilize the regulatory 409:6 and loss control -- loss control security -- they all 409:7 had different names for them -- teams at the various 409:8 chains. 409:9 In our interaction -- in our business 409:10 interactions with the retail national accounts, they 409:11 all had very strong centralized control of their 409:12 pharmacies and their inventories, and we wanted to 409:13 leverage the resources to -- they had to help us with 409:14 understanding, know your customer. 409:15 And, again, our view was if you understood 409:16 how one retail national account pharmacy operated in	V315A.19

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409:17 a given chain, they all fundamentally operated the
409:18 same way because of the heavy centralized control
409:19 that they had.
409:20 Q. Mr. Walker, how would you
409:21 characterize McKesson's efforts to comply with its
409:22 regulatory responsibilities?
409:23 A. I would -- I would -- I would say
409:24 that it is a core competency and something that
409:25 individuals, particularly in our operations group,
410:1 get at the very beginning of their career. You know,
410:2 both our hourly associates, but especially our
410:3 management teams. So because we're so regulated,
410:4 compliance is a key component of what we do. And
410:5 performance is based on that. There's -- if there's
410:6 issues that are there, it can affect the individual's
410:7 performance reviews.
410:8 So from a cultural standpoint, we strive
410:9 to -- you know, strive to be -- or strive to be, and
410:10 I believe continue to strive to be, a very compliant
410:11 organization and accept that responsibility readily.
410:12 MS. HENN: Thank you very much, Mr. Walker.
410:13 I have no further questions.

Defendants' Counters = 00:53:11
Total Time = 00:53:11